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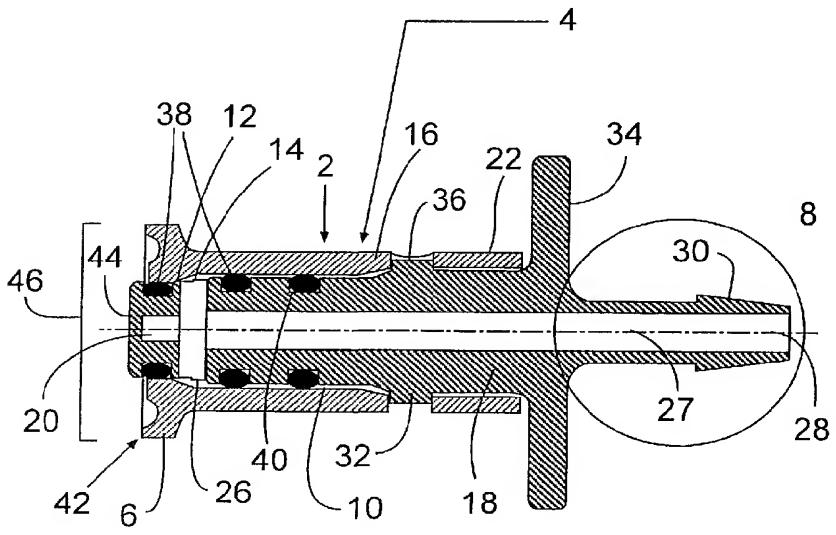
(54) **Title:** DISPOSABLE, STERILE FLUID TRANSFER DEVICE



(57) **Abstract:** The present invention relates to a sterile transfer device for fluids, be they liquids or gases. It is comprised of a body having a bore formed through at least a portion of its interior. Preferably, it is a central bore formed through the entire length of the body. Contained within the bore is a movable plunger. The body has a first and a second end. The first end contains a face designed to be attached to the upstream component. The second end is connected to a downstream component such as a filter, pipeline, sample bag and the like. The plunger has corresponding first and second ends. The first end of the plunger when it the closed position is in alignment with the face of the body which combined form a steamable surface and a sterile barrier against the environment to the rest of the interior of the body, the plunger and downstream components.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DISPOSABLE, STERILE FLUID TRANSFER DEVICE

The present invention relates to a disposable, sterile fluid transfer device. More particularly, it relates to a disposable sterile fluid transfer device, preferably in the form of a connector or valve for use in the pharmaceutical and biopharmaceutical industry.

BACKGROUND OF THE INVENTION

In the pharmaceutical, biotechnology and even food, beverage and cosmetics industries, it is often desired to provide a processing system that is capable of handling fluids in a sterile manner. This is designed to prevent unwanted, often dangerous organisms, such as bacteria as well as environmental contaminants, such as dust, dirt and the like from entering into the process stream and/or end product. It would be desirable to have a completely sealed system but this is not always possible with the processes that take place in production.

There is a need for the introduction or removal of materials from the process stream in order to add components of the product, such as media or buffers to a bioreactor; withdraw samples from the process stream to check for microbial contamination, quality control, process control, etc; and to fill the product into its final container such as vials, syringes, sealed boxes, bottles and the like.

Typically, the systems have been made of stainless steel and the system is exposed to live steam before use and then cleaned with chemicals such as caustic solutions after use to ensure that all contaminants are removed.

Steaming is the most effective means of sterilization. The use of steam in a set system is known as steaming in place or SIP. Saturated steam carries 200 times the BTU heat transfer capacity of heated air because of the latent heat released by the steam as it changes from vapor to liquid.

Several disadvantages exist with the use of steam. Any connections to or openings of the system made after the system has been SIP'd is an aseptic (but not sterile) connection or opening. This increases the risk of contamination of the entire system. One typically uses alcohol wipes or an open flame to clean the components to be connected, (e.g. connecting a sample collection bag to a system after SIP has occurred) and thus minimize the risk of contamination.

Also the high temperatures and pressure differentials of the steam make the selection of filter materials and components very difficult and limited and even then an accidental pressure differential at high temperatures can cause a filter, membrane or other non-steel component to fail.

Additionally, such systems that are reused need to undergo rigorous testing and validation to prove to the necessary authorities that the system is sterile before each use. The expense of validation as well as the cleaning regiment required is very high and very time consuming (typically taking 1 to 2 years for approval). In addition, some components are very difficult to adequately clean after use in preparation for their next use. Manufacturers are looking for ways to reduce both their costs and the time to market for their products. One possible approach is to adopt an all disposable system that is set up in a sterile fashion, used and then thrown away.

The present invention provides a connector that can be used in either the traditional steel system or disposable system which provides both a means for steam sterilizing the mating point of the connector to the system as well as providing a sterile downstream area or component, in pre-sterile condition, that can be disposed of after use and not be recleaned.

SUMMARY OF THE INVENTION

The present invention relates to a sterile transfer device for fluids, be they liquids or gases. It is comprised of a body having a bore formed through at least a portion of its interior. Preferably, it is a central bore formed through the entire length of the body. Contained within the bore is a movable plunger. The body has a first and a second end. The first end contains a face designed to be attached to the upstream component. The second end is connected to a downstream component such as a filter, pipeline, sample bag and the like. The plunger has corresponding first and second ends. The first end of the plunger when it the closed position is in alignment with the face of the body which combined form a steamable surface and a sterile barrier against the environment to the rest of the interior of the body, the plunger and downstream components.

The downstream components are assembled to the device and it is placed in the closed position. The entire device and downstream components are sterilized, such as with gamma radiation. In use the device and downstream components are attached by the face to the upstream component such as a filter outlet, a tank outlet, a "T" of a pipe and secured in place. The system and the face of the device are then steam sterilized in place. The device is

then selectively opened when needed establishing a sterile pathway through the device to the downstream components.

IN THE DRAWINGS

Figure 1 shows a cross sectional view of a first embodiment of the present invention in a closed position.

Figure 2 shows a cross sectional view of the first embodiment of the present invention of Figure 1 in an open position.

Figure 3 shows a cross sectional view of the first embodiment of the present invention of Figure 1 mounted to an upstream component.

Figure 4 shows a cross sectional view of a second embodiment of the present invention in a closed position.

Figure 5 shows a cross sectional view of a second embodiment of the present invention of Figure 3 in an open position.

Figure 6 shows a cross sectional view of another embodiment of the present invention.

Figure 7 shows a cross sectional view of another embodiment of the present invention.

Figure 8 shows a cross sectional view of another embodiment of the present invention.

Figure 9A shows a perspective view of a locking mechanism of the present invention in unopened condition.

Figure 9B shows a perspective view of the locking mechanism of 9A of the present invention in the opened condition.

Figure 9C shows a perspective view of the locking mechanism of 9A of the present invention in the reclosed position.

Figure 10A shows a perspective view of a locking mechanism of the present invention in unopened condition.

Figure 10B shows a perspective view of the locking mechanism of 10A of the present invention in the opened condition.

Figure 10C shows a perspective view of the locking mechanism of 10A of the present invention in the reclosed position.

Figure 11A shows a perspective view of a locking mechanism of the present invention in unopened condition.

Figure 11B shows a perspective view of the locking mechanism of 11A of the present invention in the opened condition.

Figure 12A shows a perspective view of a locking mechanism of the present invention in unopened condition.

Figure 12B shows a perspective view of the locking mechanism of 12A of the present invention in the opened condition.

Figure 12C shows a perspective view of the locking mechanism of 12A of the present invention in the reclosed position.

Figure 13 shows a perspective view of a locking mechanism of the present invention in unopened condition.

Figures 14 shows an alternative design of the present invention.

Figures 15 shows another embodiment of the device of the present invention.

Figures 16A- I show other embodiments of the device of the present invention in cross sectional view.

Figure 17 shows the device of the present invention in one potential application in which there is a sterile to nonsterile connection.

Figure 18 shows the device of the present invention in one potential application in which there is a sterile to sterile connection.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is a sterile fluid transfer device, preferably in the form of a connector or a valve.

A first embodiment of the present invention is shown in Figure 1. The device 2 is formed of a body 4 having a first end 6 and a second end 8. The body 4 also has a bore 10 extending in this embodiment from the first end 6 to the second end 8. The bore 10 as shown is formed of three sections each with a different diameter. There is the first bore section 12 which has a first set diameter, a transition bore section and a second bore section which has a second set diameter that is greater than the first set diameter of the first bore section 12. The transition bore section 14 is arranged between the first and second bore sections 12, 16 and has an outwardly tapering diameter along its length with the diameter of the transition section 14 adjacent the first bore section 12 being equal to the first set diameter and the diameter of the transition section 14 adjacent the second bore section 16 being equal to the second set diameter. The diameter of the transition section between the first and second bore sections is preferably a linear outward progression between the two bore sections.

Contained within the bore is a plunger 18 which has a shape corresponding to that of the bore 14. The plunger has a first portion 20 having a diameter equal to or less than that of the diameter of the first bore section, a second plunger portion 22 having a diameter equal to or less than that of the second bore section and a transitional portion 24 between the first and the second plunger portions 20, 22 having an outwardly tapered diameter between the first and second plunger portions 20, 22 equal to or less than the diameter of the transition bore section 14. The plunger 18 also contains one or more openings 26 in either the transitional portion 24 or the first or second portions 20, 22 as well as a fluid channel 27 that forms a fluid connection to a downstream component or tubing (not shown).

As shown, the farthest part 28 of the second portion 22 contains a barb design 30 to connect to the next downstream component. The plunger also contains several preferable elements that are useful but not necessary to the invention. Included among these are a cam 32 and a connector handle 34. The cam 32 rides in a cam slot 36 formed in the body 4 and together is used to limit the length of travel of the plunger 18 in the bore 14.

The device is shown in Figure 1 in the closed position. One or more seals 38 are arranged along the length of the plunger 18 to form a liquid tight seal between various portions of the plunger 18 and the bore 14 when they are in the closed or open positions. As shown the seals 38 are contained in grooves 40.

The device 2 is attached to an upstream component or pipe by a sanitary flange 42 formed as part of the body 4. In the closed position the flange 42 and the farthestmost end of the first portion of the plunger 44 form a face 46 against the rest of the system. The flange 42 can be attached to the upstream component or pipe by a clamp such as a Tri-Clover™ fitting, Ladish™ fitting, ClickClamp™ clamp or the like. This face 46 is capable of withstanding steam treatment when in the device is in the closed position as will be described in more detail below.

Figure 2 shows the device 2 of Figure 1 in the open position. To the extent that the same reference numbers apply to both Figures 1 and 2 they have been kept the same.

In Figure 2, the plunger has been moved from the closed position of Figure 1 to an open position. The farthestmost end of the first portion of the plunger 44 has been moved back from the face 46 providing a passageway 48 to the bore 14 and the one or more openings 24 and the fluid channel 26 forming a fluid connection between the upstream 50 and downstream sides 52 of the device 2. As shown, the plunger is moved rearward or downstream and rotated at the same time, as evidenced by the movement of the cams 32 in the cam slot 36.

Figure 3 shows the device 2 of Figure 1 mounted to an upstream component 54, in this instance a "T" pipe and a downstream component 56, in this instance a piece of hose or plastic pipe. Also shown is liquid tight seal 58 formed between the flange of the device 2 and a flange 60 (clamp not shown).

Figure 4 and 5 show an embodiment of the present device 61 in which there is no fluid passage formed in the plunger. Instead, the body contains a port 62 which provides the fluid connection to the downstream component 64, in this instance a piece of plastic piping. As shown in the closed position, the farthestmost end 66 of the first portion 68 of the plunger 70 seals off the downstream side of the device 61 from the upstream component 72. The port 62 is shown as being at a 90 degree angle to the length of the body, but it may be any other desired angle.

As shown in Figure 5, when the device of Figure 4 is opened, the farthestmost end 66 of the first portion 68 of the plunger 70 has been moved back from the face 72 providing a passageway 74 to the bore 76 and the port 62 so as to provide fluid communication between the upstream component 72 and the downstream component 64 through the device 61.

As shown in Figures 1-5, the seals may be mounted on the plunger of the device. Further, the seals shown in Figures 1-5 are O-rings, either pre-formed and retained within grooves on the plunger or formed in place in the grooves of the plunger. However, if desired, different configurations of seals and their placements can be used. For example, Figure 6 shows some seals 80 formed on the plunger 82 with other seals 84 held in grooves 86 in the inner surface of the bore 88.

Figure 7 shows an embodiment with a linear or gland seal 90 is retained within a groove 92 on the inner wall of the body 94 and other seals 96 attached to the plunger 98 in grooves 100.

Figure 8 shows a similar design to that of Figure 7 except that the gland seal 90 is formed on the outer wall 91 of the plunger 98 and other seals 96 are attached to the plunger 98 in grooves 100.

As this is device is provided in a sterile condition, i.e. the interior of the system and any component connected downstream of the device is pre-sterilized such as with gamma radiation, ethylene gas or the like and shipped in a sterile condition, some type of use indicator would be helpful so one knows when a system has been used and should therefore be replaced.

Figure 9A shows a first embodiment of an indicator useful on the present invention. As shown in the Figure9A, the body section 102 distal from the steamable face 104 has a series of

one or indentations or locking recesses or fixed pawls 106. The plunger 108 has a mating detent 110 which is located in one of the recesses before the device is sterilized. The device is shipped in this sterile condition with the detent remaining in the recess. In fact, the detent/recess combination works to ensure that the device doesn't accidentally open due to vibration or handling during shipping.

The device is then taken from its sterile container in the closed position of 9A and attached by its face to the system. The face is then steam sterilized. The device is then opened by rotating the handle to an open position as shown in Figure 9B.

When the device is closed after use, the handle 112 of the plunger 108 is capable of moving the detent 110 past the first recess and into the second recess 106 as shown in Figure 9C. This provides a visual indication to the user that the device is no longer sterile. In addition, it provides a manual indication to the user that the device has been used as the detent 110 has to be turned past the two recesses 106, each with an affirmative clicking action before the device can be opened. Moreover, one can design the walls of the farthermost (used condition) recess 106 so that the movement out of the recess requires an extraordinary amount of force to again indicate to the user that the device has been used and shouldn't be reused.

Figure 10A shows another embodiment of an indicator useful on the present invention. As shown in the Figure 10A, the body section 113 distal from the steamable face (not shown) has a series of one or indentations or locking recesses or fixed pawls 106 as well as one or more breakaway tabs 114. The plunger 108 has a mating detent 110 which is located in one of the recesses 106 before the device is sterilized as well as a breaking bar 116. The device is shipped in this sterile condition with the detent remaining in the recess and the breaking bar being positioned behind the breakaway tab.

The device is then taken from its sterile container in the closed position of 10A and attached by its face (not shown) to the system. The face is then steam sterilized. The device is then opened by rotating the handle 112 to an open position as shown in Figure 10B. In doing so the breaking bar116 rotates past and over the breakaway tab 114, causing it to be bent over or removed altogether.

When the device is closed after use, the handle 112 is capable of moving the detent 110 past the first recess 106 and into the second recess 106A as shown in Figure 10C.

Figures 11A and B show a plastic feature extending from the body that forms another breakaway (or bend-away) indicator. Figure 11A, shows the valve in its shipped (or pre-sterilized) position. It is intended that when the valve is opened, this protruding feature will break away or at least bend away from its original position, thereby indicating that the valve has

been actuated and should not be used again once it has been subsequently closed. Figure11B shows the valve in the open position, showing the tab feature as being bent.

Figure 12A shows another embodiment of an indicator useful on the present invention. As shown in the Figure 12A, the body section 113 distal from the steamable face (not shown) has a series of one or indentations or locking recesses or fixed pawls 106 as well as one or more tab retainers 120. The plunger 108 has a mating detent 110 which is located in one of the recesses 106 before the device is sterilized as well as a breakaway or fold over tab 122. The device is shipped in this sterile condition with the detent remaining in the recess and the breaking bar being positioned behind the breakaway tab.

The device is then taken from its sterile container in the closed position of 12A and attached by its face (not shown) to the system. The face is then steam sterilized. The device is then opened by rotating the handle 112 to an open position as shown in Figure 12B. In doing so the tab 122 in tab retainer 120 rotates out of the retainer 120, causing it to be bent over or removed altogether.

When the device is closed after use, the handle 112 is capable of moving the detent 110 past the first recess 106 and into the second recess 106A as shown in Figure 12C with the tab 122 if it remains being bent up and not being returning to the retainer 120.

As an alternative or in addition to any of the mechanisms discussed above, as shown in Figure 13 one may use a shrink wrap indicator 130 over the device or at least the handle portion 132 of the plunger 134 and the surrounding body 136 of the device to indicate that the device is in an unopened condition.

As an alternative to the face of the device as shown in Figure 1, one may use a foil 160, metal or plastic, such as PEI, PEEK, polysulphones, aluminum, stainless steel and the like, adhered to the body portion 162 of the face 164 and used to form the sterile seal as shown in Figure 14. It is then pierced or penetrated by the plunger 166 to establish a fluid flow. A rubber septum in lieu of the foil could also be used. A scored surface can also be used. The foil may be adhered in a variety of manners that are well known in the art such as heat sealing, vibration welding such as ultrasonic welding, solvent bonding and through the use of adhesives such as epoxies and urethanes.

Figure 15 shows another embodiment of the present invention. In this embodiment the body of the device is formed as an integral component of a pipe. Preferably the pipe is made of a steam resistant plastic (described below) or alternatively, it may be made of a metal such as stainless steel so long as it contains the necessary features of the present invention. The body

can be formed as an arm of the piece as shown. The plunger (as shown being similar to that of Figure 1) is then inserted into the body of the piece.

Figures 16 A- I show several other connectors devices that fall within the present invention. Figure 16A is similar to the valve design of Figure 14A. It is comprised of a body 180, and a plunger 181 contained with in a bore 182 of the housing. The plunger has a fluid channel185 connecting it in fluid communication to the rest of the downstream side of the device and beyond. A face 183 is formed by the outermost portion of the body 180 and plunger 181. Unlike the embodiment of Figure 1, the bore 182 is essentially linear as is the plunger 181. As shown, the device is in its open position. The plunger 181 rather than retracting into the bore 182, is extended out from the bore to expose an opening or openings 184 so as to create fluid communication between one en d and the other end of the device.

Figure 16B shows a close up variant of the design of Figure 16A. In this variant, the opening 184B is formed at a right angle to the fluid channel 185B only on one side of the plunger.

Figures 16C and D show a close up cross-sectional view of another embodiment. In this variant, the upstreammost portion of the plunger 181C is in the form of series of spring fingers 186. The plunger 181C is pulled back into the bore 182C to open the device as shown in Figure 16D. Fluid then flows into the bore 182C, into openings 184C through the fluid channel 185C to the downstream component.

Figures 16E and F show a close up cross-sectional view of another embodiment. In this variant, the upstreammost portion of the plunger 181E is in the form of compression nut 187. The plunger 181E is pulled back into the bore 182E to open the device as shown in Figure 16F. Fluid then flows into the bore 182E, into openings 184E through the fluid channel 185E to the downstream component.

Figure 16 G shows another embodiment of the present invention. In this design, the plunger 181G is actually mounted to move laterally within the bore 182G of the housing 180G in a push/pull fashion to open and close the device. The face 183G is formed of the upstream end of the body and the plunger 181G as shown.

Figure 16 H shows a rotatable device with the body 180H being formed of two pieces 188A and 188B. The plunger 181H is contained within a portion of the bore 182H as shown. The plunger as shown is in the closed position. The face 183H is formed by the upstreammost portions of the plunger 182H and the body portion 188B. Also as shown the upstream component is attached to the plunger 181H. As the plunger is rotated from its closed to its open

position, the fluid channel 185H of the plunger aligns with a fluid channel 189 of body portion 188B to establish fluid communication through the device.

Figure 16I shows another variant of the rotational design. Here the Plunger 181I is retained in the bore 182I of the body 180I by a groove 190 and abutment 191. When the plunger 181I is rotated to its open position, fluid may pass through the bore 182I into the fluid channel 185I through opening 184I.

Figure 17 shows the device of the present invention in one potential application in which there is a sterile to nonsterile connection. As shown the fluid transfer device 200 of the embodiment shown in Figure 3 is attached by its face (not shown) to a connection point 204 such as a "T" fitting on a process pipe 206 as shown. A clamp 202 holds the adjoining and mating faces (not shown, but see Figure 3 for details of the mating assembly) of the device and the pipe 206 together in a liquid tight arrangement. The exit of the device 208 here in the form of a barb is connected to a tube 210 which in turn is connected to a collection bag 212. In use, the device 200 is in a closed position and has the tube 210 and bag 212 connected to it. The device with the tube and bag are then gamma sterilized (i.e. by gamma irradiation) or otherwise sterilized.

The device with the tube and bag is then attached to the pipe by the device face (not shown) by the clamp 202. The face is then steam sterilized along with the remainder of the system and is ready for use. When it is desired to fill the bag 212, one simply opens the device 200 by rotating the handle 214 which moves the plunger (not shown) away fro m the face creating an opening into the bore for the fluid to flow out the exit 208 through tube 210 and into the bag 212. Once the bag 212 is full, the handle is rotated the opposite direction to close the bore to the fluid. The bag 212 can then be closed off via a clamp or hemostat (not shown) and removed for further processing or use.

Figure 18 shows a system using the device of the present invention wherein two sterile devices can be connected together. As shown, one can use a connector 300 formed of four interconnecting arms 302 A, B, C and D the end of each arm 302 A,B, C and D having a mating flange 304 A,B, C and D. a first sterile transfer device 306 of the present invention in attached to arm 302A and a second device 308 is attached to a second arm 302B. A live steam line 310 is attached to arm 302C and a steam/condensate trap 312 is attached to arm 302D. Alternatively, one could attach a sterile barrier filter as taught by PCT/US01/47425, filed December 3, 2001 and available from Millipore Corporation of Bedford, Massachusetts to arm 302D to remove the condensate after steaming.

Devices 306 and 308 are attached to other components of the system (not shown) and as with the embodiment of Figure 14 are presterilized such as with gamma radiation before assembly the connector 300.

After assembly, steam enters through line 310 to sterilize the entire interior of connector 300 and the steamable faces of the devices 306 and 308. The steam then shut off and the steam/condensate is removed to the trap 312 which is then shut off from the connector 300. Devices 306 and 308 are then opened to form a sterile to sterile connection between them.

Other uses will be found for these devices. For example, they can be used to isolate a steam fragile component, such as some filters with steam sensitive membranes, in a process line. The filter especially in the form of a disposable capsule can be attached to the device and presterilized (such as by gamma). The device can then be connected to the line which is then steam sterilized and the device is then opened to provide fluid flow to the filter. If desired the inlet and outlet of the filter can contain such devices the outermost ends of which have the steam sterilizable face. Alternatively, a device can be attached to each end of a length of tube to form a sterile transfer pipe. Other uses can also be made of the present invention. Additionally, the connector of the present invention can be connected or actually molded into a disposable plastic container such as disposable process bag for the manufacture and transfer of biotech products. Such bags are readily available from companies such as Hyclone of Utah and Stedim of France.

The device is formed a plastic material and may be formed by machining the body and plunger assemblies and then applying the necessary seals and the like, or preferably by molding the body and the plunger separately and assembling them together with the necessary seals and other components.

The device may be made of any plastic material capable of withstanding in line steam sterilization. The temperature and pressure of such sterilization is typically about 121°C and 1 bar above atmospheric pressure. In some instances, it may be desirable to use even harsher conditions such as 142°C and up to 3 bar above atmospheric pressure. The body and at least the face of the plunger should be capable of withstanding these conditions. Preferably, the entire device is made of the same material and is capable of withstanding these conditions. Suitable materials for this device include but are not limited to PEI (polyetherimide), PEEK, PEK, polysulphones, polyarlysulphones, polyalkoxysulphones, polyethersulphones, polyphenyleneoxide, polyphenylenesulphide and blends thereof. Alternatively, one can make the face portion from ceramic or metal inserts alone or that are overmolded with a plastic

cover One can also form a polymeric face with a metal outer layer using plasma coating processes.

The seals of the present invention can be made of a variety of materials typically used for making resilient seals. These materials include but are not limited to natural rubber, synthetic rubbers, such as silicone rubbers, including room temperature vulcanizable silicone rubbers, catalyzed (such as by platinum catalysts) silicone rubbers and the like, thermoplastic elastomers such as SANTOPRENE ® elastomers, polyolefins such as polyethylene or polypropylene, especially those containing gas bubbles introduced either by a blowing agent or entrained gas such as carbon dioxide, PTFE resin, thermoplastic perfluoropolymer resins such as PFA and MFA resins available from Ausimont, USA of Thorofare, New Jersey and E.I. DuPont de Nemours of Wilmington, Delaware, urethanes, especially closed cell foam urethanes, KYNAR® PVDF resin, VITON® elastomer, EPDM rubber, KALREZ resin and blends of the above.

Suitable materials for molded in place seals can be curable rubbers, such as room temperature vulcanizable silicone rubbers, thermoplastic elastomers such as SANTOPRENE ® elastomers, polyolefins such as polyethylene or polypropylene, especially those containing gas bubbles introduced either by a blowing agent or entrained gas such as carbon dioxide and elastomeric fluoropolymers

Other materials used in the devices should also be FDA grade components such as FDA grade silicones, PTFE resins and the like.

The present invention provides a sterile and steam sterilizable connecting device for fluid transfer. It may be single actuation (one open one close) or it may be multiple actuations with a single sterile connection (multiple openings and closings so long as the sterile connection upstream and downstream is maintained). Additionally, with the use of multiple seals or seals of long length, one is able to ensure that the sterility of the device is maintained even with multiple actuations.

What is claimed:

1) A sterile transfer device for fluids comprised of a body having a bore formed through at least a portion of its interior, a movable plunger contained within the bore, the body having a first and a second end, the first end containing a face designed to be attached to the upstream component, the second end being connected to a downstream component, the plunger having a corresponding first and second end, the first end of the plunger when in a closed position being in alignment with the face of the body, which combined, form a steamable surface and a sterile barrier against the environment to the rest of the interior of the body, the plunger and downstream components.
2) The device of claim 1 wherein the bore is a central bore formed through the entire length of the body.
3) The device of claim 1 wherein the fluid is selected from the group consisting of liquids and gases.
4) The device of claim 1 wherein the device is formed of a plastic selected from the group consisting of polyetherimides(PEI), PEEK, PEK, polysulphones, polyarylsulphones, polyalkoxysulphones, polyethersulphones, polyphenyleneoxide, polyphenylenesulphide and blends thereof.
5) The device of claim 1 wherein the device is formed of polyetherimides(PEI).
6) The device of claim 1 wherein the device is capable of forming a sterile to sterile connection.
7) The device of claim 1 wherein the device is capable of forming a sterile to non- sterile connection.
8) he device of claim 1 wherein the first end containing a face has a liquid impermeable steam resistant layer attached to it.
9) The device of claim 1 wherein the first end containing a face has a liquid impermeable steam resistant layer attached to it and wherein the layer is selected from the group consisting of plastic and metal foils.
10) The device of claim 1 wherein the first end containing a face has a liquid impermeable steam resistant layer attached to it and wherein the layer is selected from the group consisting of plastic and metal foils selected from the group consisting of PEI, PEEK, polysulphones, aluminum and stainless steel.

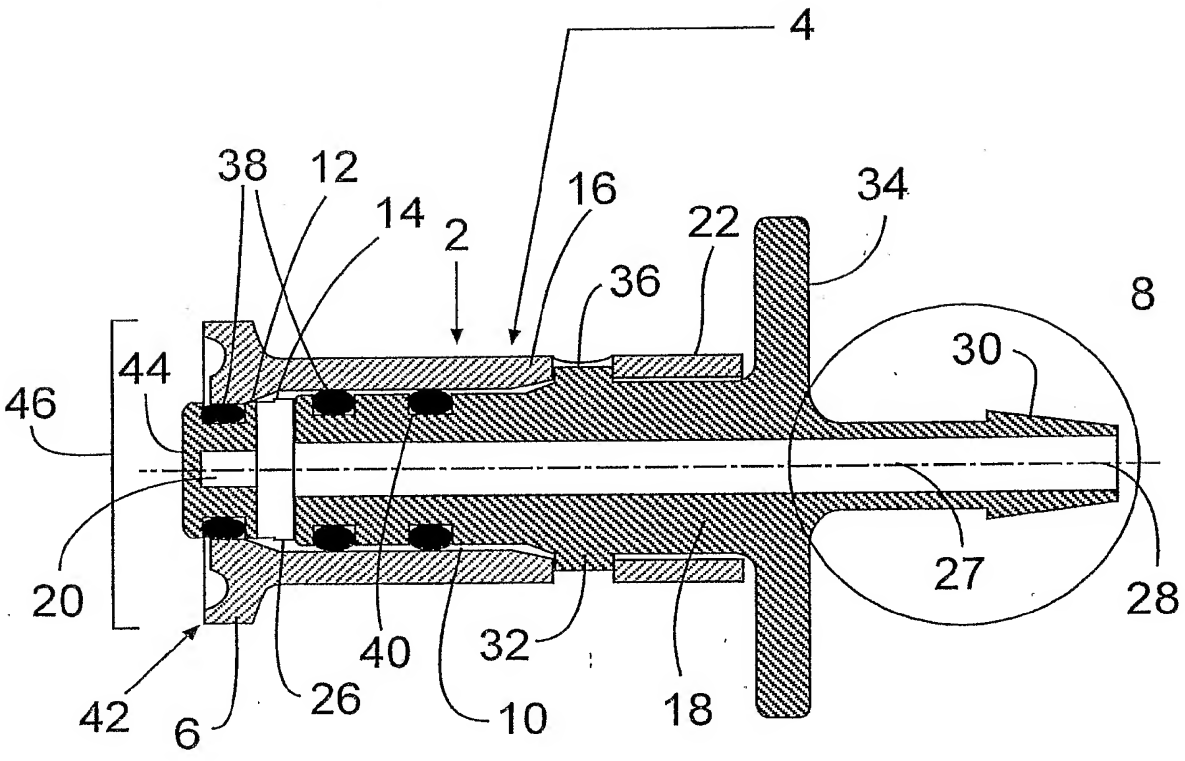

Figure 1

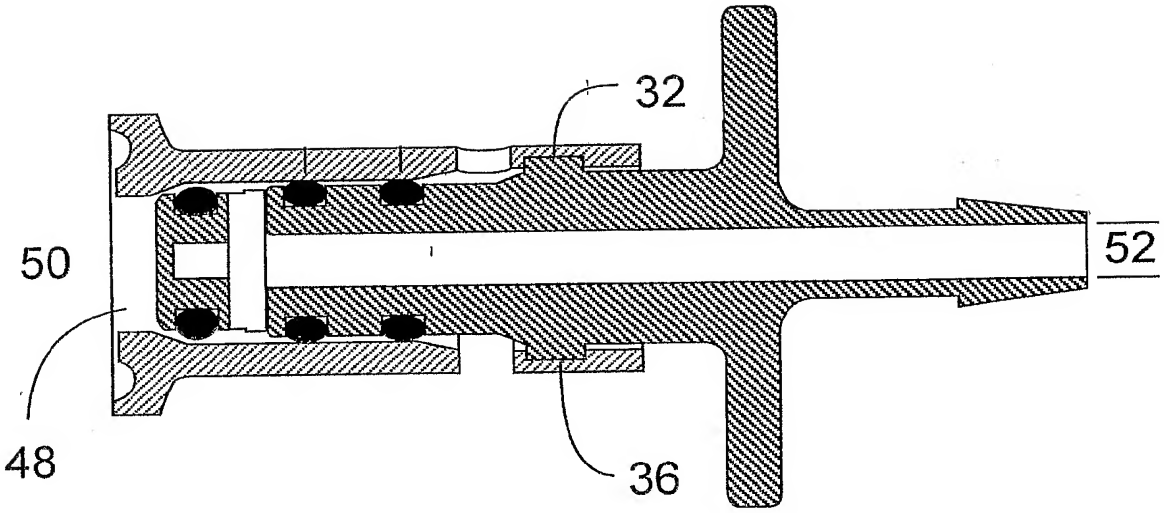

Figure 2

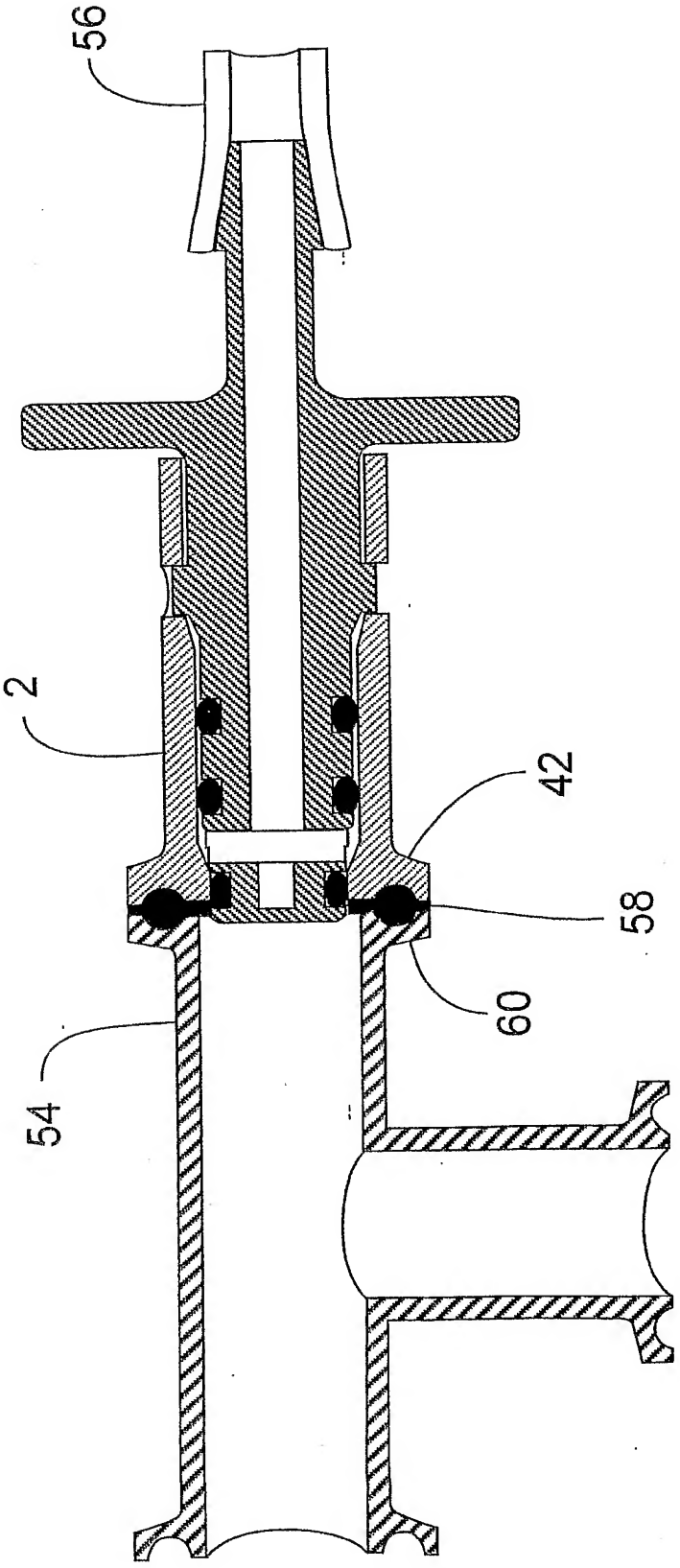

Figure 3

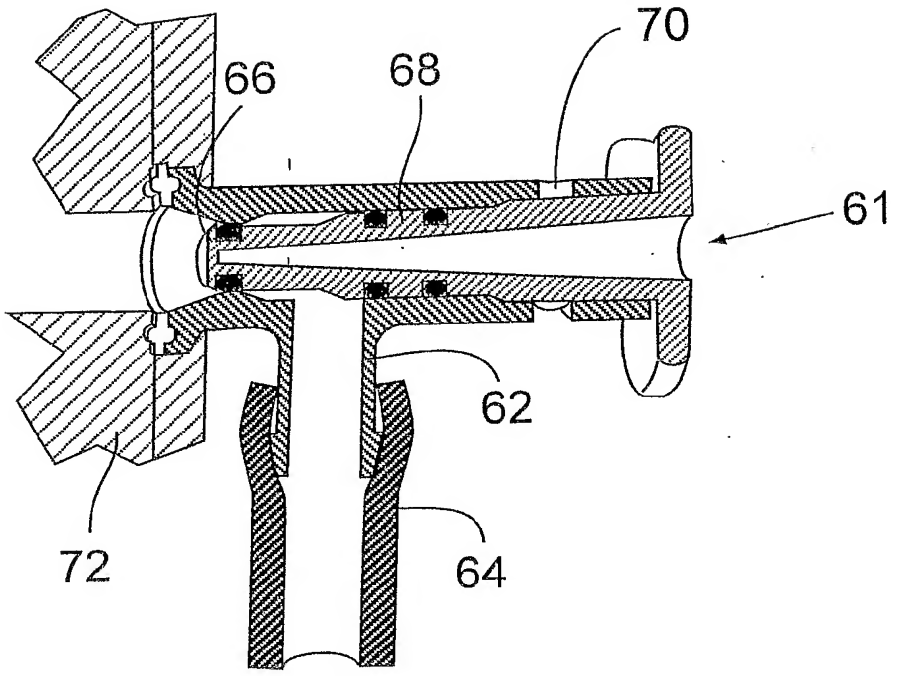

Figure 4

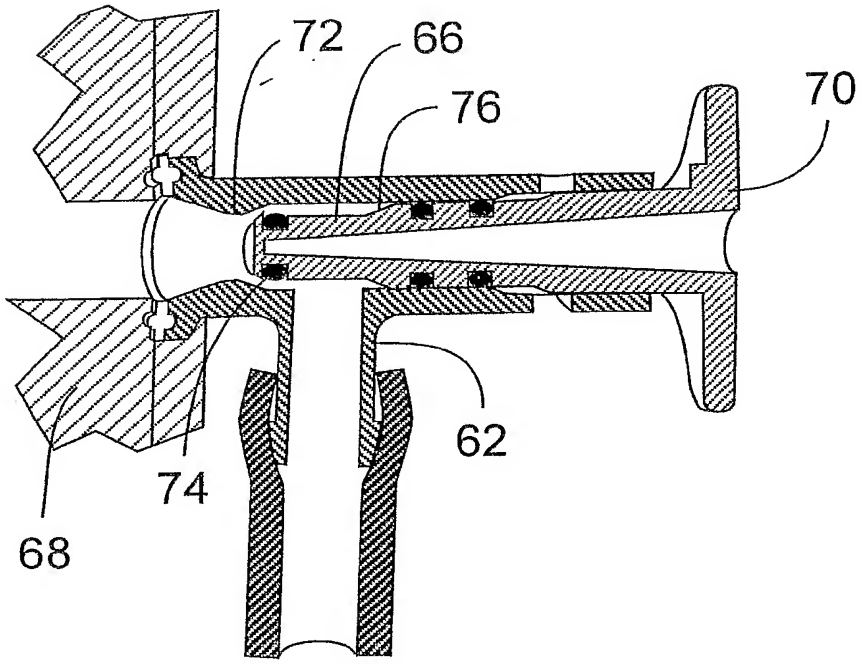

Figure 5

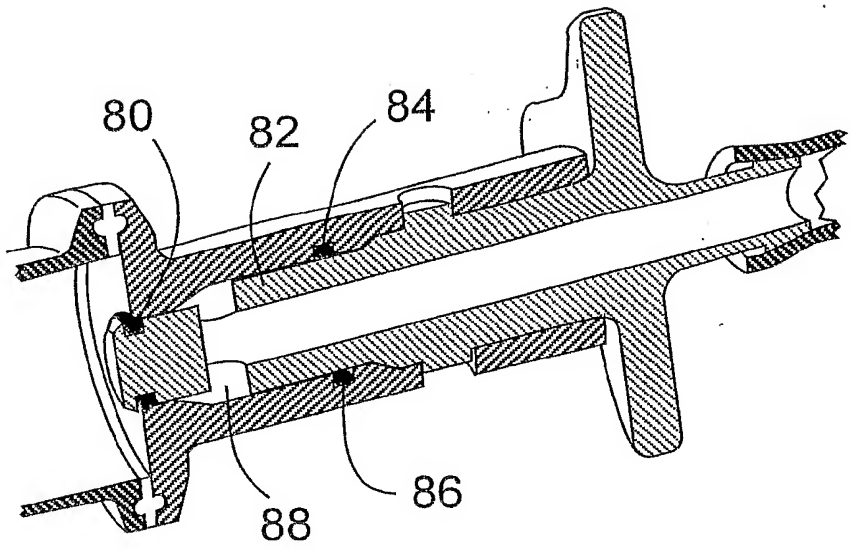

Figure 6

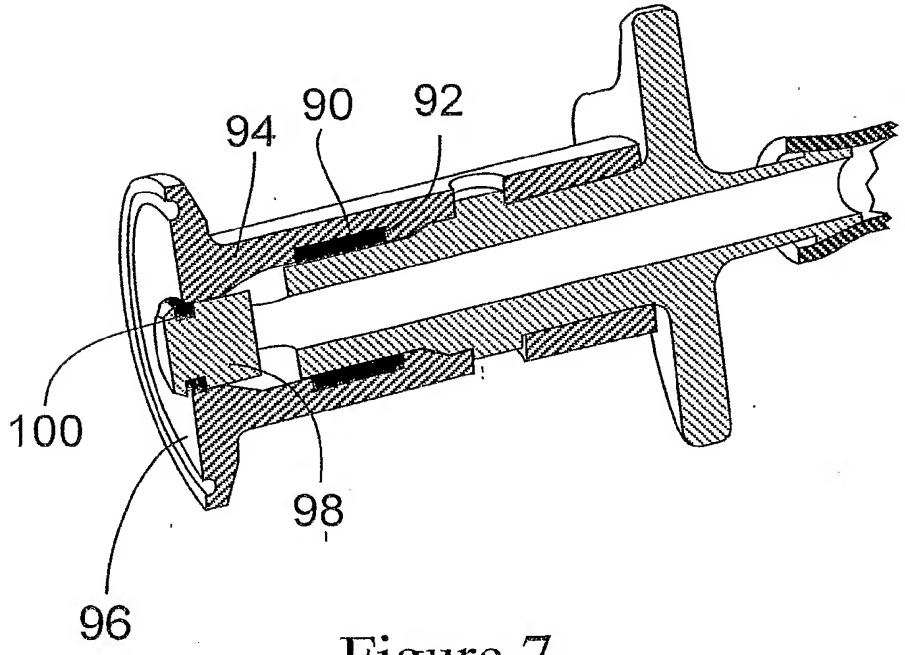

Figure 7

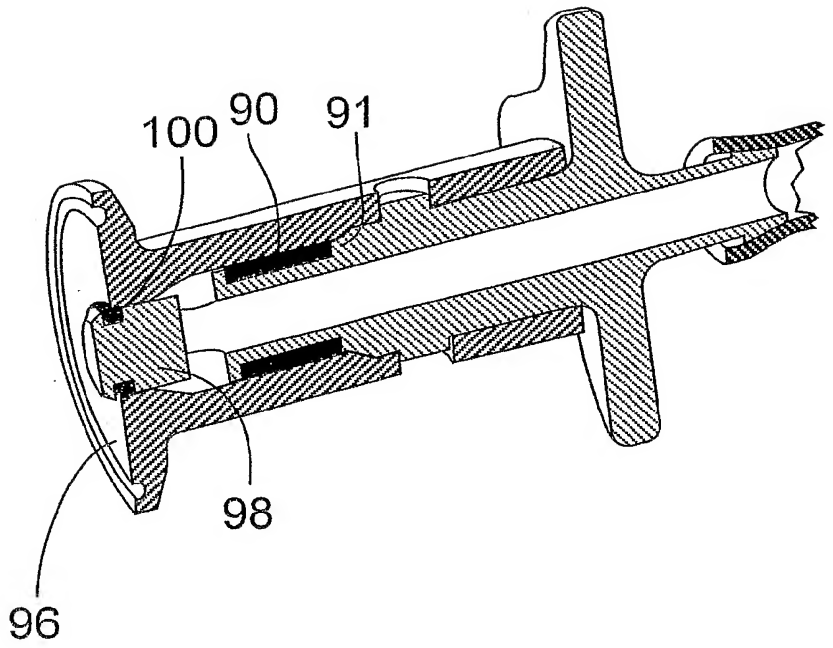

Figure 8

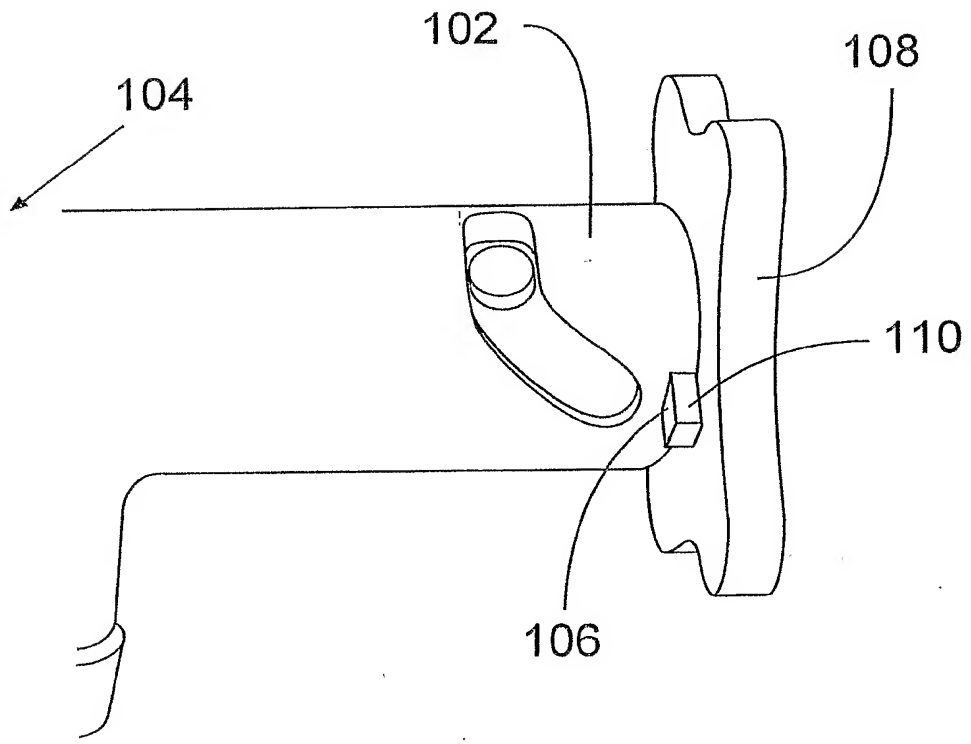

Figure 9a

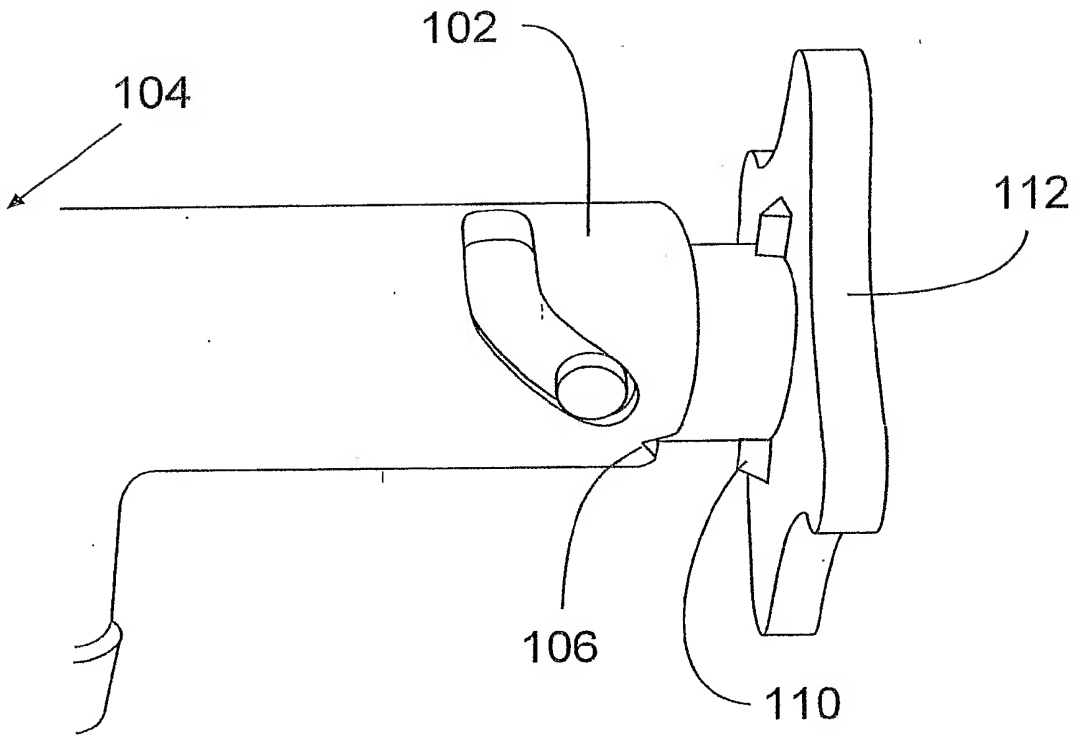

Figure 9b

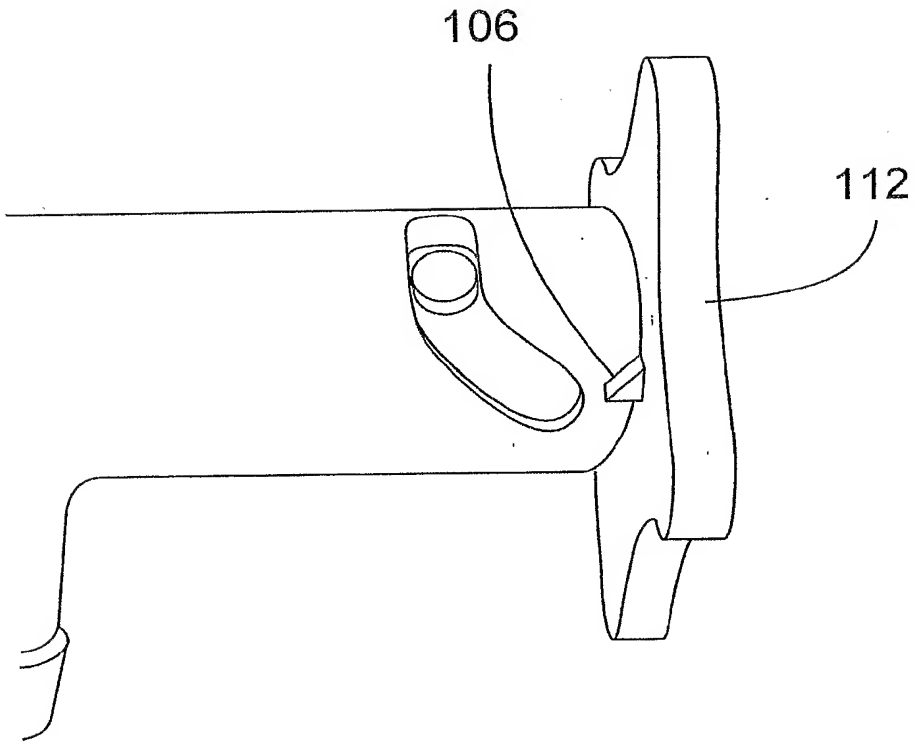

Figure 9c

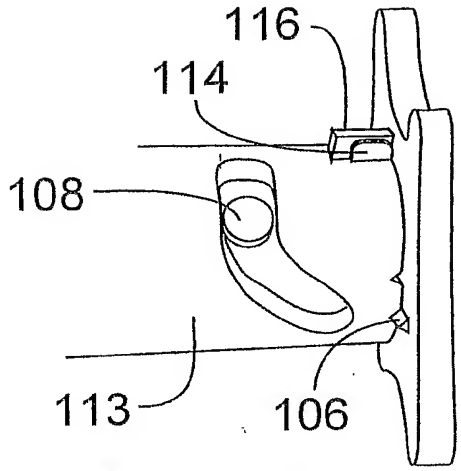

Figure 10a

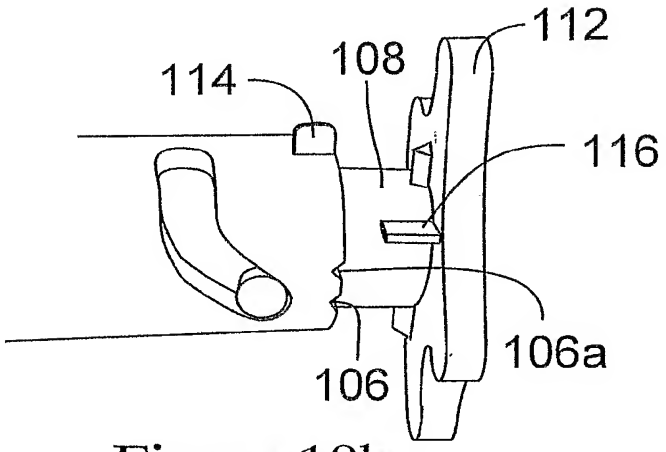

Figure 10b

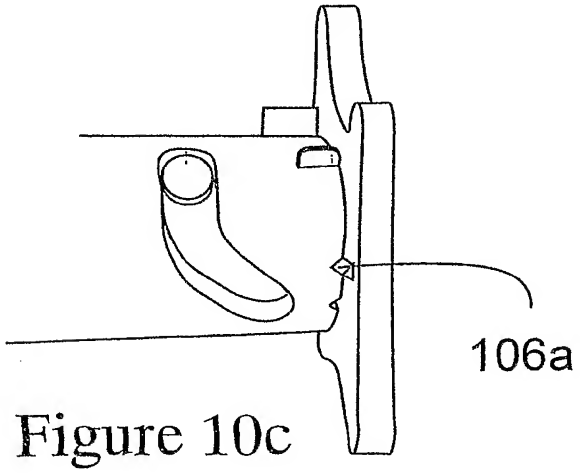

Figure 10c

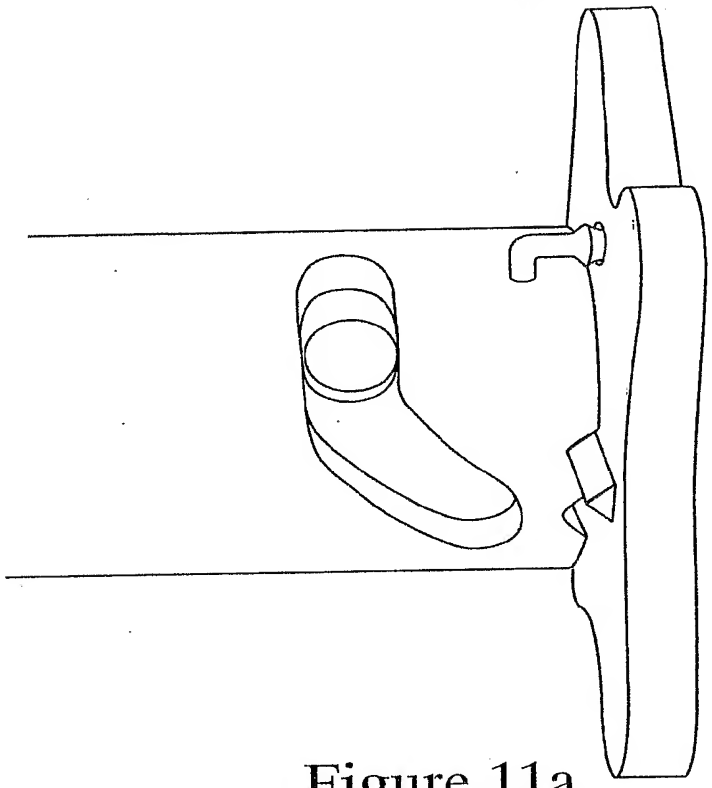

Figure 11a

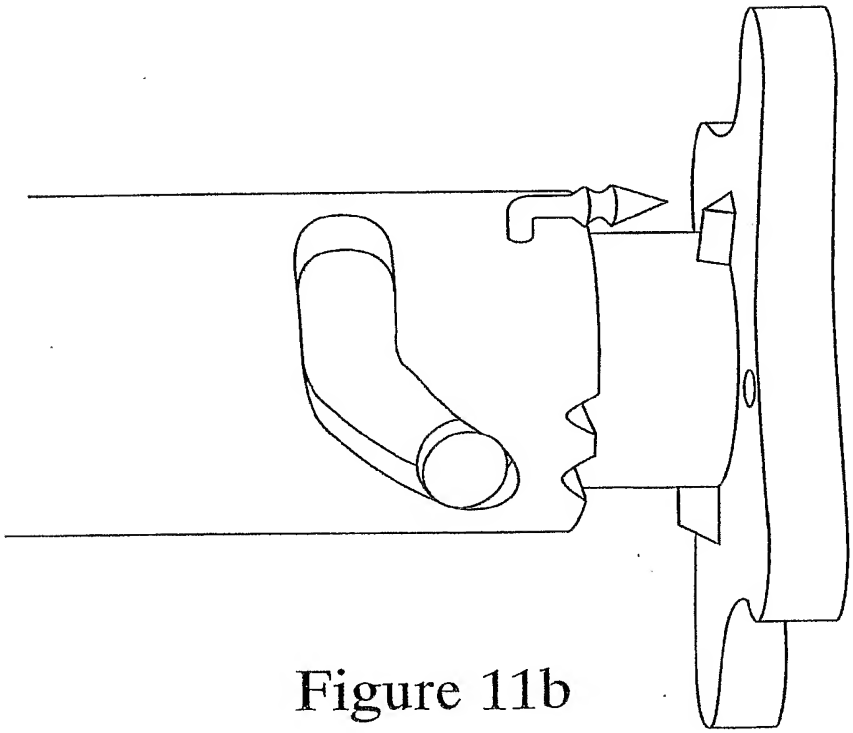

Figure 11b

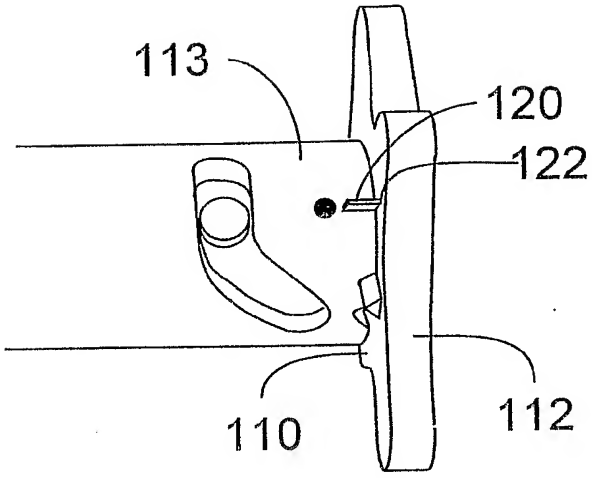

Figure 12a

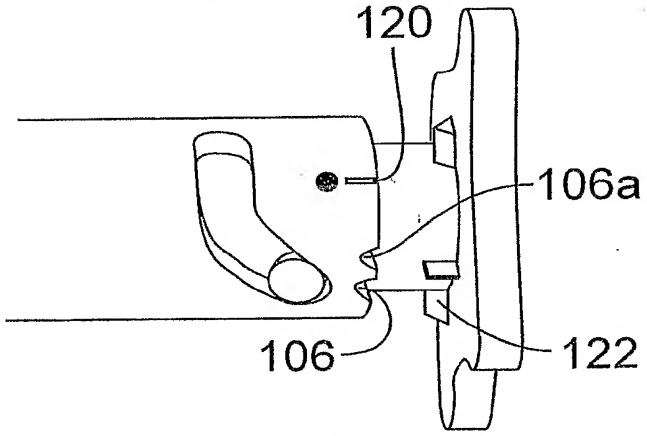

Figure 12b

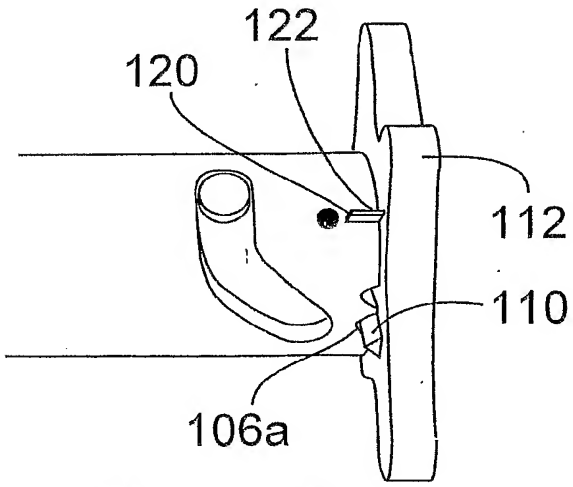

Figure 12c

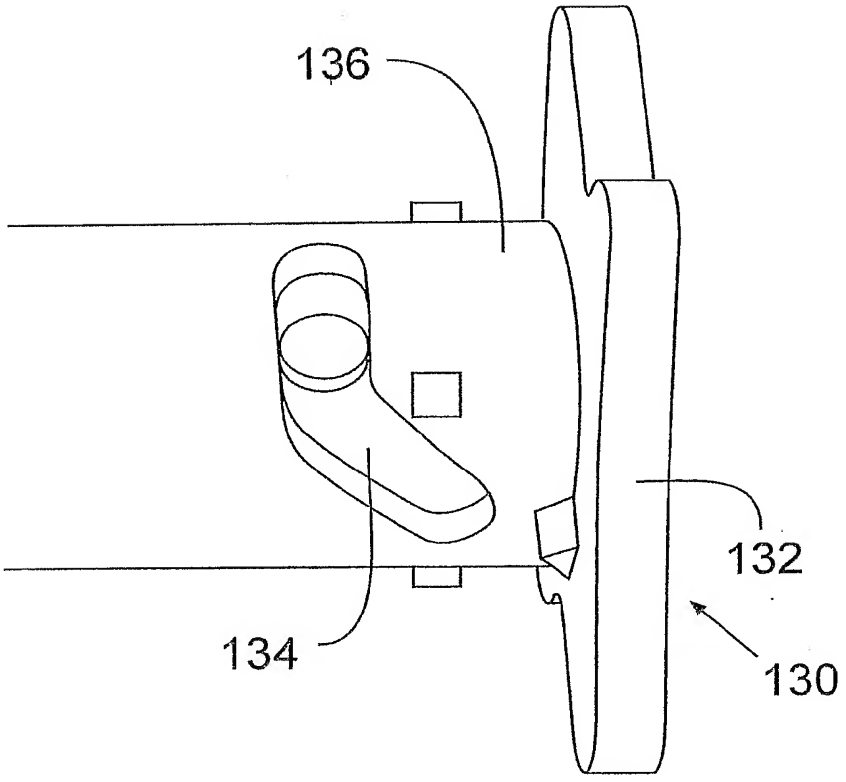

Figure 13

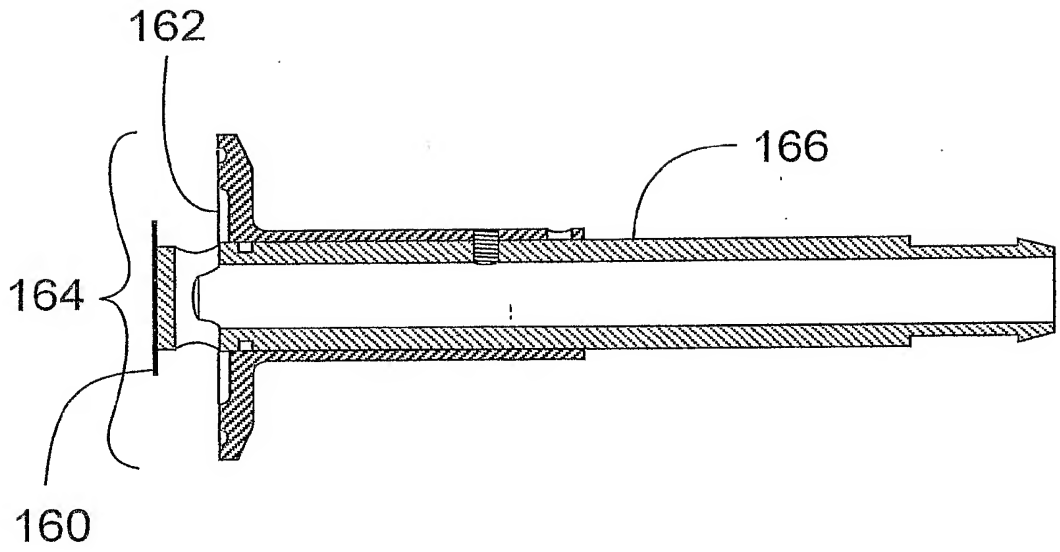

Figure 14

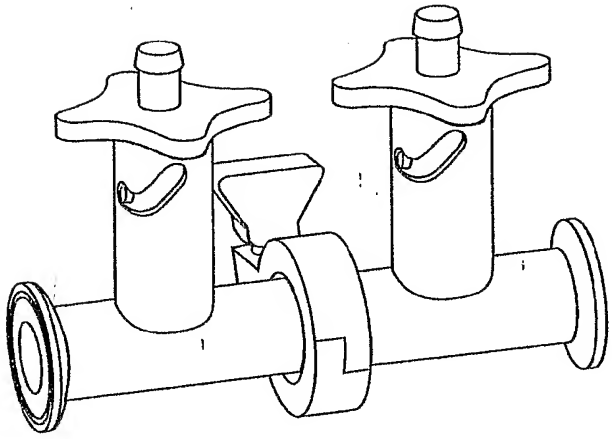

Figure 15

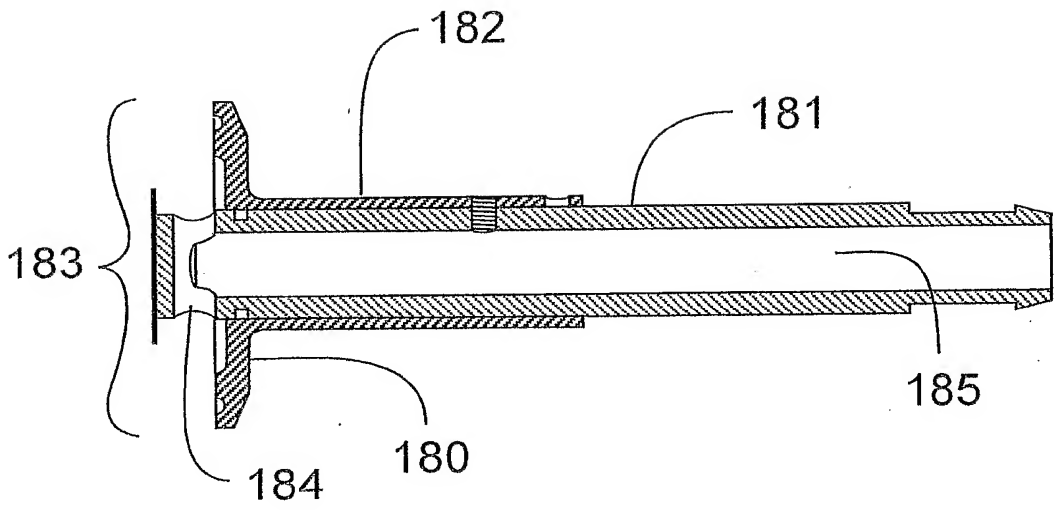

Figure 16a

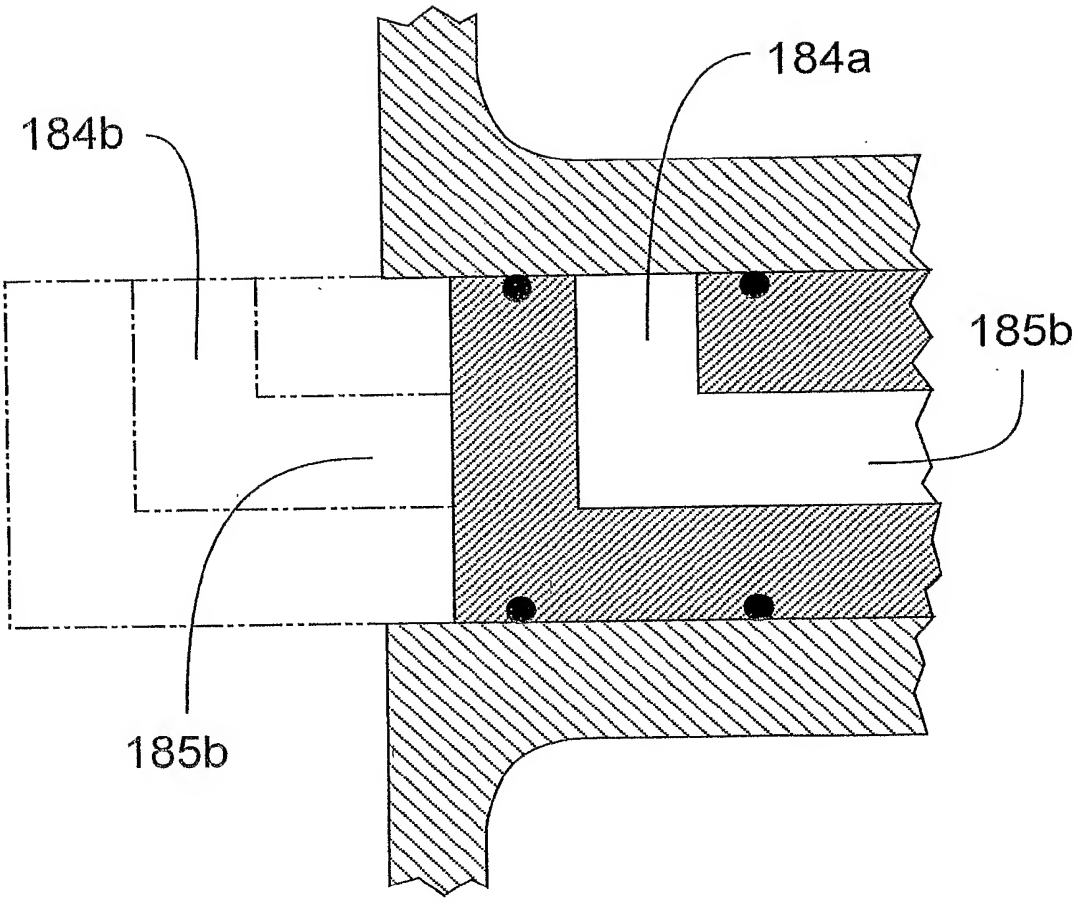

Figure 16b

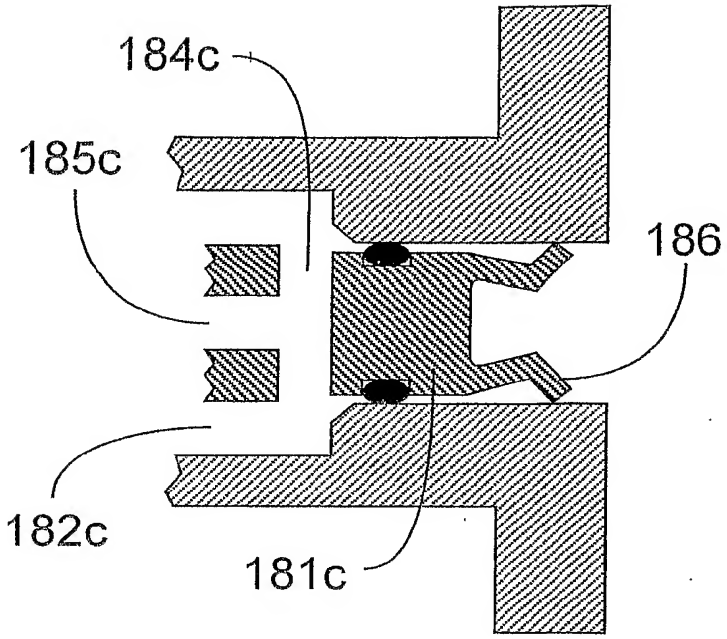

Figure 16c

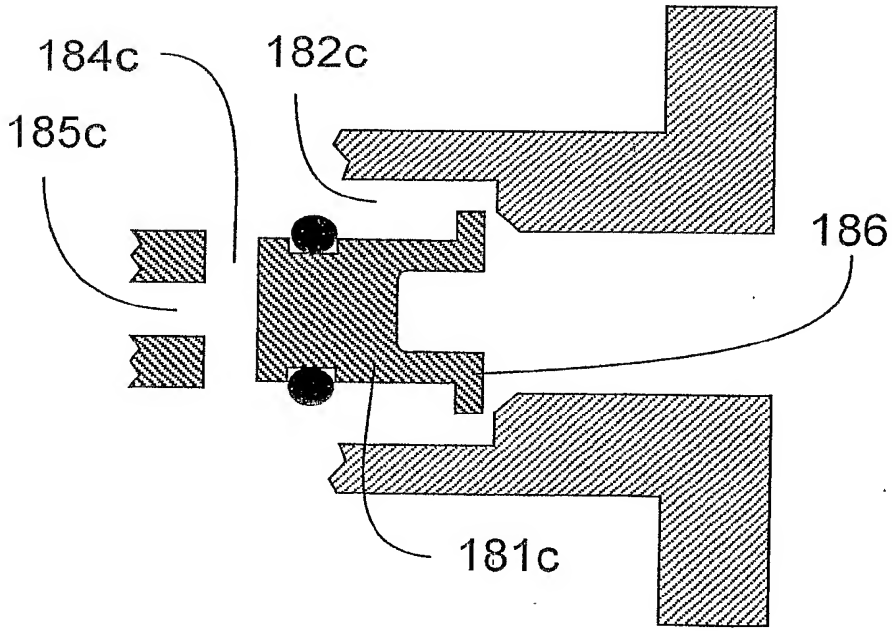

Figure 16d

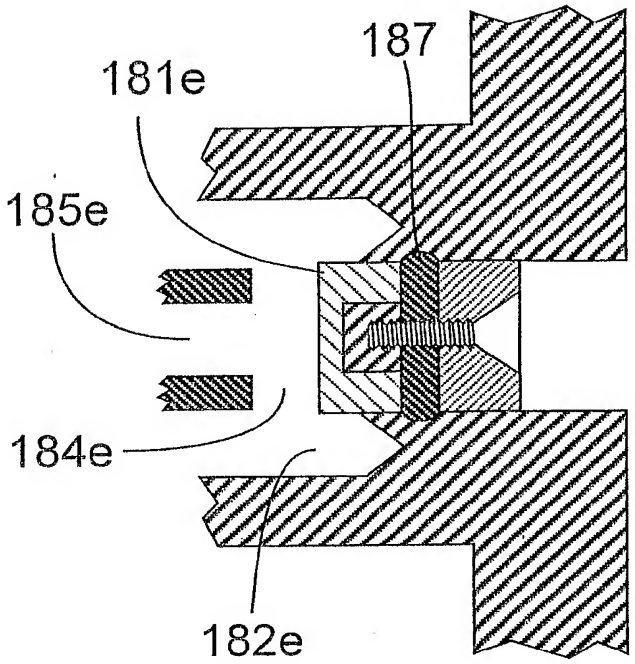

Figure 16e

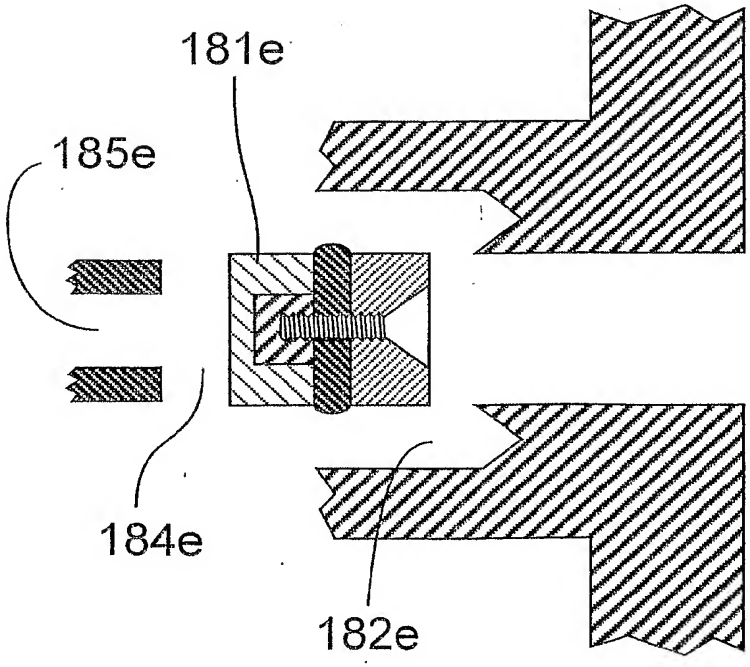

Figure 16f

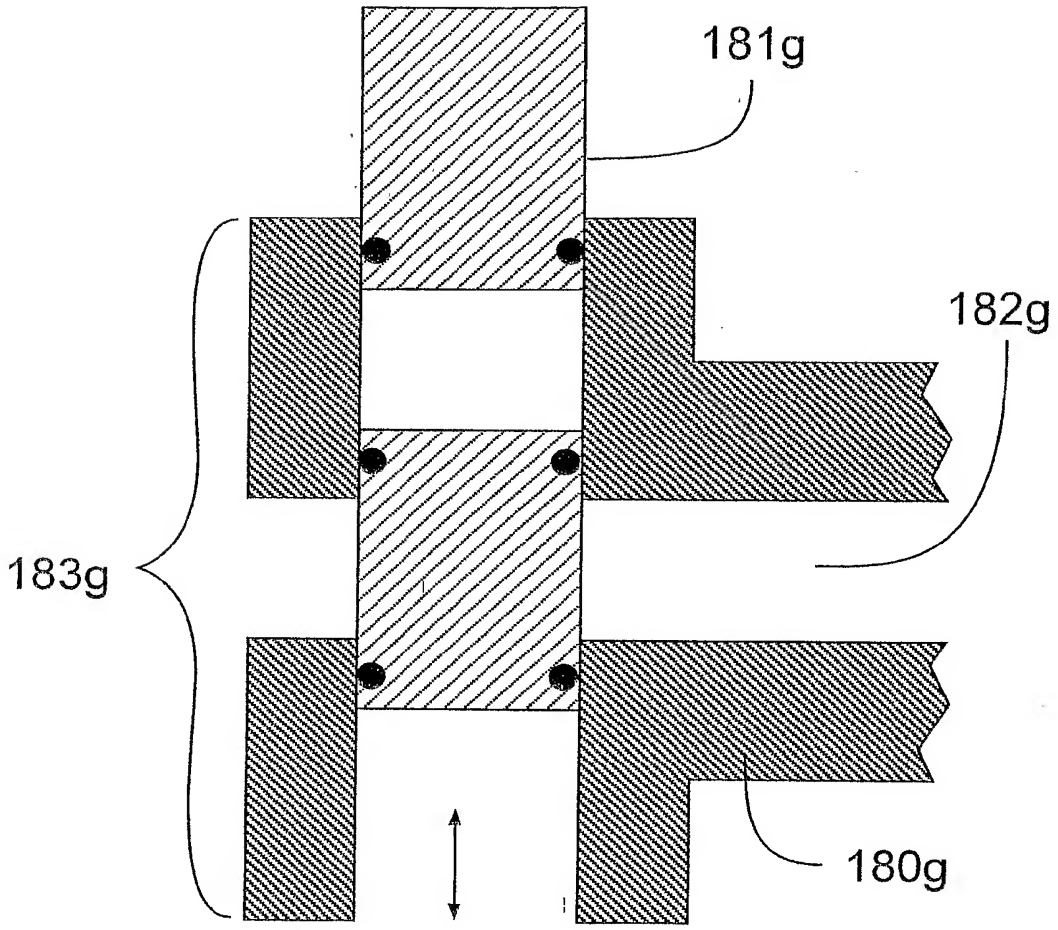

Figure 16g

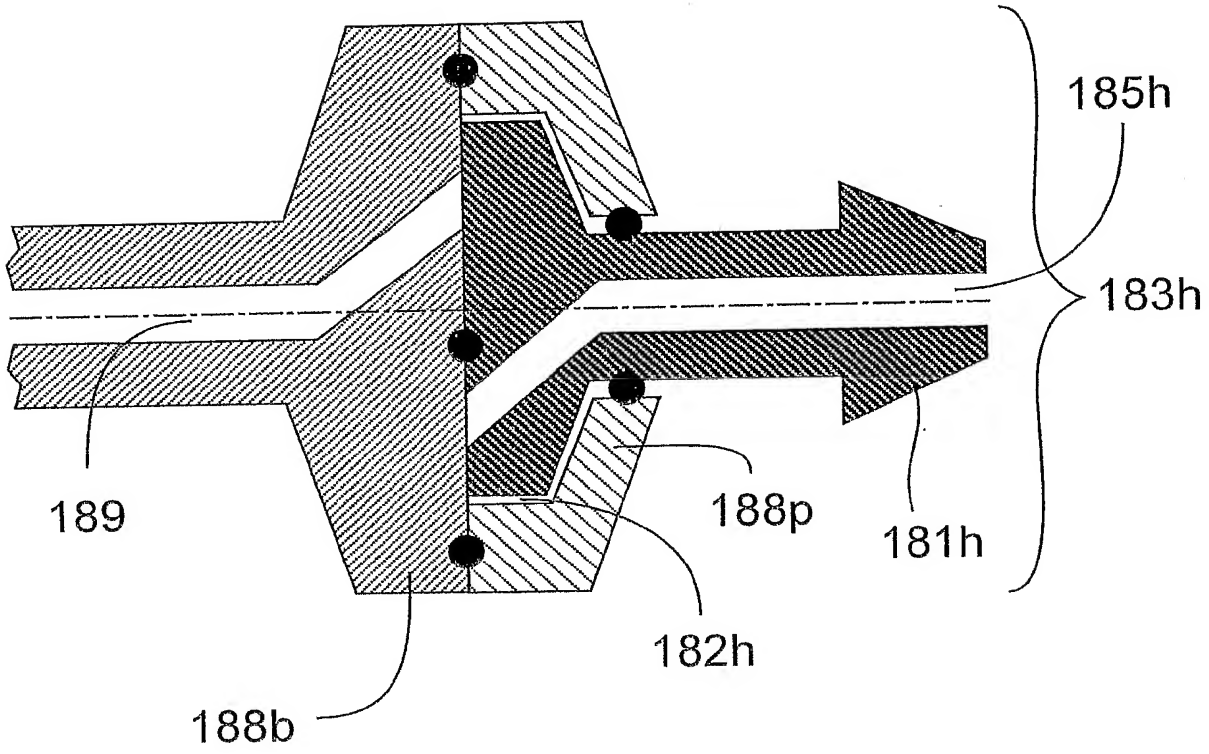

Figure 16h

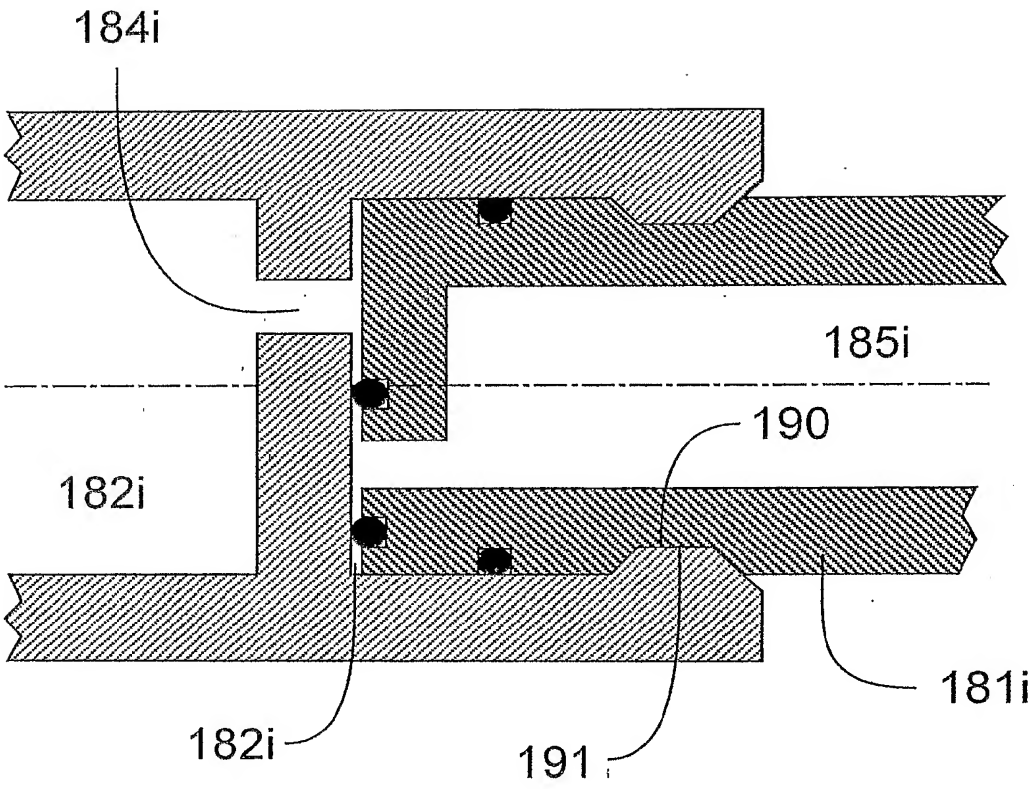

Figure 16i

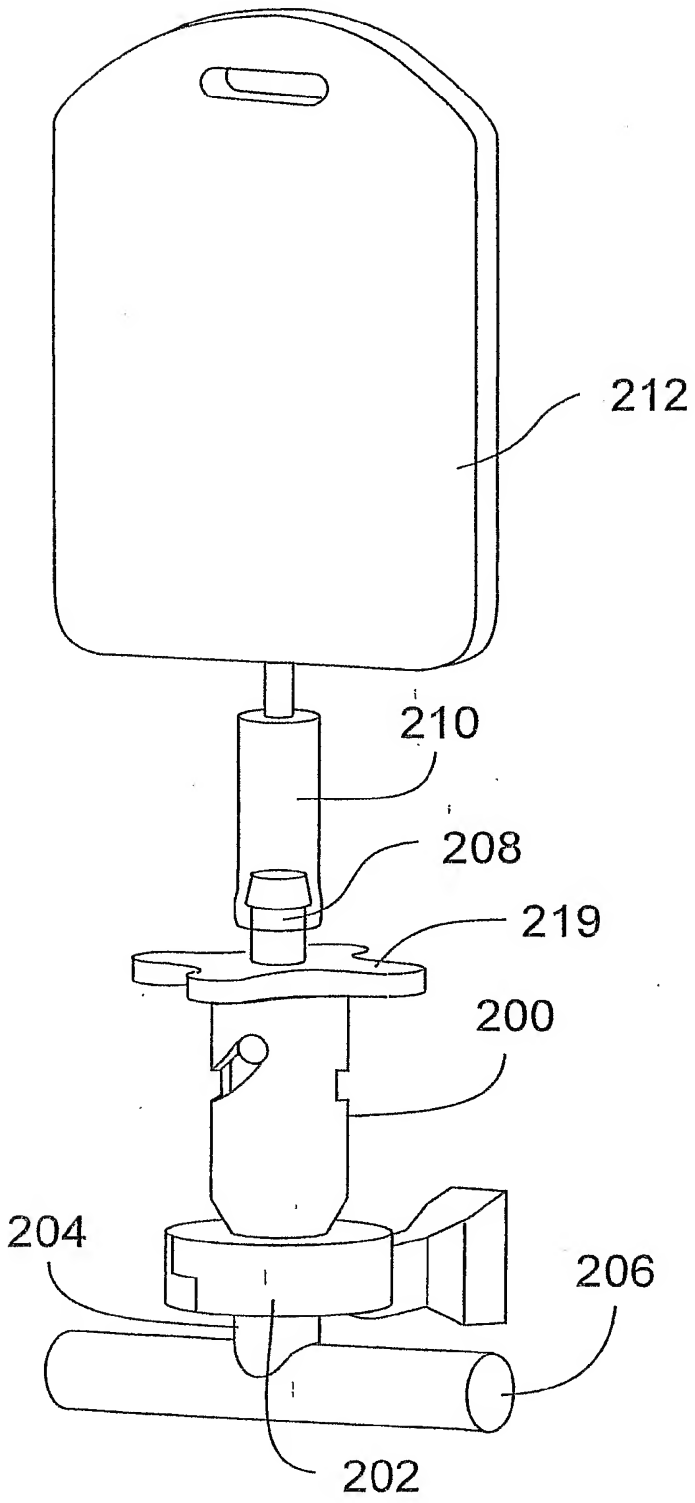

Figure 17

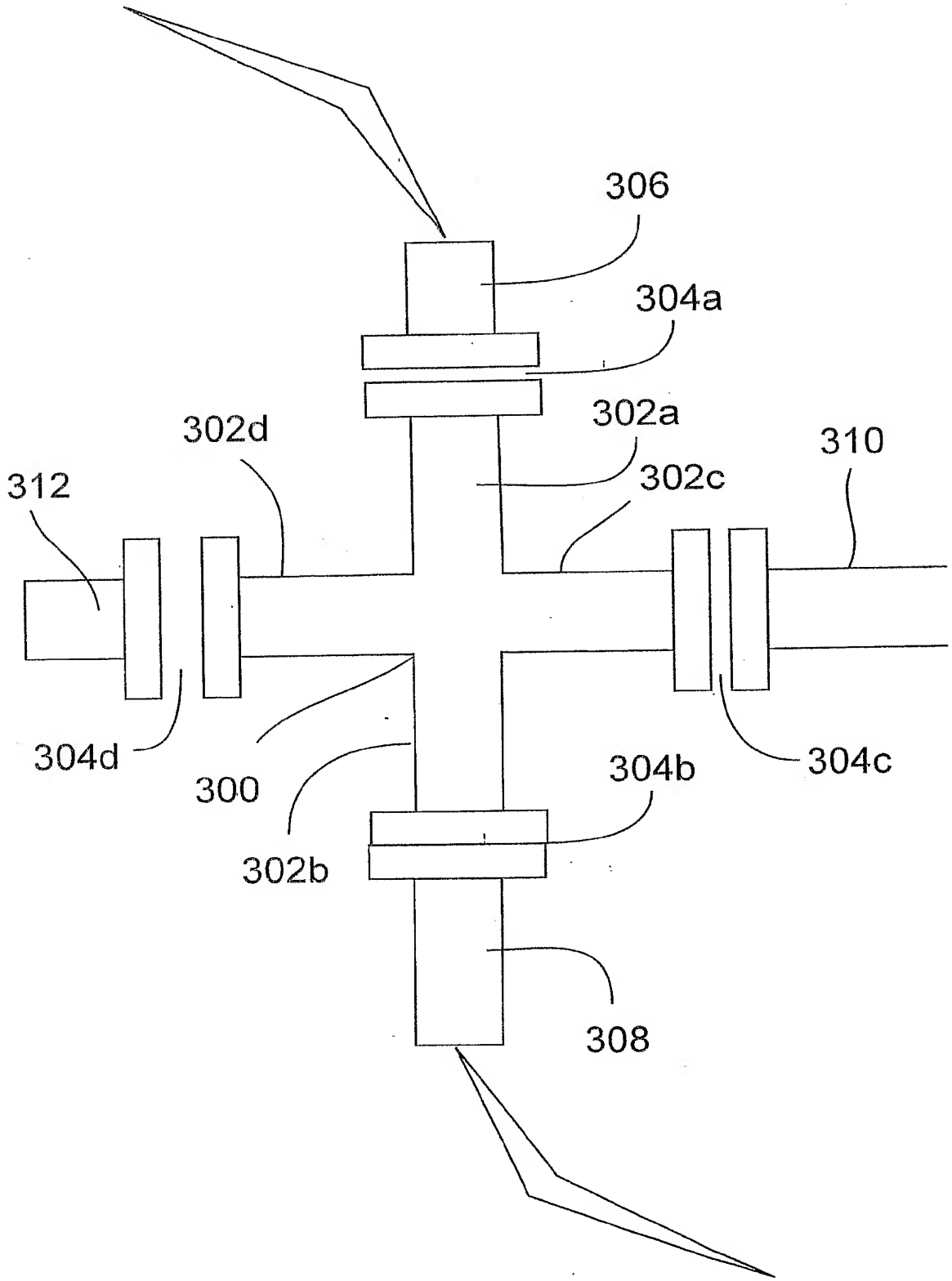

Figure 18

INTERNATIONAL SEARCH REPORT

Intern ~ I Application No
PCT/US 03/12927

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M39/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M B65D A61J A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 684 050 A (IVAC CORP) 29 November 1995 (1995-11-29) column 8, line 39 -column 9, line 14 column 11, line 4 -column 12, line 12 figures 3,4,7,8	1-3,6,7
Y	---	4,5
Y	US 4 838 877 A (MASSAU BRUCE A) 13 June 1989 (1989-06-13) column 6, line 32 - line 40 column 8, line 47 - line 49	4,5

X	US 5 360 413 A (LEASON MICHAEL H ET AL) 1 November 1994 (1994-11-01) column 2, line 53 -column 3, line 68; figures 3,7,10	1-3,6,7

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 July 2003	06/08/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Schönleben, J

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INTERNATIONAL SEARCH REPORT

Interr l Application No
PCT/US 03/12927

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	DE 100 39 196 A (FRESENIUS MEDICAL CARE DE GMBH) 28 February 2002 (2002-02-28) column 4, line 34 -column 6, line 30; figure 1	1-3
A	GB 2 327 369 A (PALL CORP) 27 January 1999 (1999-01-27) page 19, line 1 - line 13	4
A	WO 98 45188 A (MENSHEN GEORG & CO KG ;HINS JOHANNES (DE)) 15 October 1998 (1998-10-15) page 6, line 19 - line 28; figures 1,2	8,9

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern. I Application No
PCT/US 03/12927

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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